

K122585

510(k) Summary
Crux Vena Cava Filter System
21 CFR 807.92

JAN 17 2013

Device Common Name: Vena Cava Filter

Applicant / Manufacturer: Crux Biomedical, Inc.
1455 Adams Drive, #1170
Menlo Park, CA USA 94025
Tel: 650-321-9903
Fax: 650-321-9904

Correspondent Contact Information: Elisa Hebb
Vice President, Clinical and Regulatory Affairs
Crux Biomedical, Inc.
1455 Adams Drive, #1170
Menlo Park, CA 94025
Tel: 650-321-9903
Fax: 650-321-9904
Email: ehebb@cruxbiomedical.com

Device Classification Regulation & Name: 21 CFR 870.3375, Cardiovascular intravascular filters

Device Classification & Product Codes: Class II, DTK

Panel: Cardiovascular

Prior FDA Document Numbers: K120402/S1 and S2

Device Proprietary Name: Crux Vena Cava Filter System

Basis of Submission: Special 510(k) based on K120402

Kit Description: Crux Vena Cava Filter System consists of:
Crux Vena Cava Filter
Crux Delivery Catheter

Number of Devices in Submission: 7014 – Crux Vena Cava Filter System – Femoral
7015 – Crux Vena Cava Filter System - Jugular

Intended Use

The Crux VCF System is indicated for the prevention of recurrent pulmonary embolism via percutaneous placement in the inferior vena cava (IVC) in the following situations:

- Pulmonary thromboembolism when anticoagulants are contraindicated
- Failure of anticoagulant therapy in thromboembolic diseases
- Emergency treatment following massive pulmonary embolism where anticipated benefits of conventional therapy are reduced
- Chronic, recurrent pulmonary embolism where anticoagulant therapy has failed or is contraindicated

The Crux VCF may be removed according to the instructions contained in the Instructions for Use section "Optional Retrieval of the Crux VCF" in patients who no longer require a vena cava filter. Retrieval of the filter can be performed by femoral or jugular approach.

Device Description – Crux Vena Cava Filter (VCF) System

The Crux VCF System is an endovascular medical device used in the prevention of recurrent pulmonary embolism (PE). The system consists of a self-expanding Nitinol filter delivered from a single-use, disposable 9Fr catheter, which can be used percutaneously to deploy the filter. The filter wireforms are composed of two opposing self-expanding Nitinol spiral elements connected at each end with Nitinol crimps. One end of each wireform is formed into a sinusoidal shaped retrieval tail to aid in retrieval of the filter using a snare. Each retrieval tail has an atraumatic plasma ball and a radiopaque tantalum marker band to facilitate visualization. There are five tissue anchors attached to the wireforms elements with Nitinol tubing. The filter is designed to treat IVC diameters of 17 to 28mm.

The Delivery Catheter for the Crux VCF is a disposable, 9Fr introducer-sheath-compatible, single-use Delivery Catheter. The filter is provided loaded in the Crux VCF System for jugular or femoral approach delivery. The Delivery Catheter is an over-the-wire system, 0.035" guidewire-compatible, and consists of a polycarbonate inner shaft and a nylon outer shaft. The polyimide inner shaft consists of the guidewire lumen and a flexible, radiopaque tracking tip and a radiopaque marker band. The outer shaft has a radiopaque marker band, a Touhy-Borst hemostasis valve and a one-way check-valve for flushing.

The filter can be retrieved with commercially available snares and sheaths via either the jugular or femoral approach.

Predicate Device Information

Predicate Device: Crux Vena Cava Filter System

510(k) Numbers: K120402

Device Manufacturer: Crux Biomedical, Inc.
1455 Adams Drive, #1170
Menlo Park, CA 94025 USA

Device Common Name: Cardiovascular Filter

Device Classification Name: 21 CFR 876.3375, Cardiovascular intravascular filters

Device Classification & Codes: Class II, DTK

Comparison to Predicate Device

Both the updated Crux VCF System and predicate device share similar designs, mode of operation and materials. The filters are the same in the subject and predicate devices. Both filters are delivered to the vena cava via transcatheter approach. When deployed, the nitinol material utilized in both the predicate and subject devices allows for self-centering of the filter. Both filters are designed with anchors to secure the filter to vessel wall and both filters can be safely retrieved via catheterization.

The primary differences between the predicate and subject devices are the design updates for the Delivery Catheter in the subject device. The design updates include a smoother tracking tip, increased radiopacity of tracking tip, an additional radiopaque marker, and an updated manufacturing process for tubing. Based on the design verification results, the updates in Delivery Catheter do not have an adverse impact on the safety and effectiveness of the VCF when compared to the predicate device.

As demonstrated in the results of the bench testing, these differences in design do not adversely affect the performance when compared to the predicate device and the devices are substantially equivalent.

Other areas of substantial equivalence with predicate device:

- Intended Use
- Indications for Use
- Target Patient Population
- Mode of Operations

Summary of Supporting Data

Crux conducted the applicable performance testing for the cited changes to the filter Delivery Catheter. Performance testing was conducted to establish substantial equivalence to the predicate device as outlined below:

- In vitro testing
 - Dimensional and Visual Inspection
 - Deployment
 - Trackability
 - Bond Strength

Conclusion

Bench test results demonstrate that the device meets the established specifications and is comparable to the predicate device supporting substantial equivalence.

The results for the updated Crux Vena Cava Filter System indicate safety and effectiveness for the proposed intended use. The results also are comparable to the established predicate device supporting substantial equivalence.

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Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

JAN 17 2013

Crux Biomedical, Inc.
c/o Ms. Elisa Hebb
Vice President, Clinical and Regulatory Affairs
1455 Adams Drive, # 1170
Menlo Park, CA 94025

Re: K122585

Trade/Device Name: Crux Vena Cava Filter System
Regulation Number: 21 CFR 870.3375
Regulation Name: Cardiovascular Intravascular Filter
Regulatory Class: Class II
Product Code: DTK
Dated: December 21, 2012
Received: December 26, 2012

Dear Ms. Hebb:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA).

You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical

device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to <http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm> for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,

Matthew G. Hillebrenner

for

Bram Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

Device Name: Crux Vena Cava Filter System (Crux VCF System)

Indications for Use:

The Crux VCF System is indicated for the prevention of recurrent pulmonary embolism via placement in the inferior vena cava (IVC) in the following situations:

- Pulmonary thromboembolism when anticoagulants are contraindicated,
- Failure of anticoagulant therapy in thromboembolic diseases,
- Emergency treatment following massive pulmonary embolism where anticipated benefits of conventional therapy are reduced,
- Chronic, recurrent pulmonary embolism where anticoagulant therapy has failed or is contraindicated.

The Crux VCF may be removed according to the instructions contained in the section "Optional Retrieval of the Crux VCF" in patients who no longer require a vena cava filter. Retrieval of the filter can be performed by femoral or jugular approach.

Prescription Use X AND/OR Over-The-Counter Use
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)



(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K122585

Page 1 of